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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
VOGEL, NANCY S

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/678,961	**Applicant(s)** SLATER ET AL.	
	Examiner Nancy T. Vogel	**Art Unit** 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.
2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☐ Claim(s) _____ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☒ Claim(s) *1-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 36 drawn to a method for the directional subcloning of DNA fragments comprising providing a first vector, a second vector, and combining the first and second vectors, classified in class 435, subclass 91.52.

II. Claims 14-26, drawn to a vector system comprising a first vector, classified in class 435, subclass 320.1.

III. Claims 27, drawn to a method for producing a vector suitable for expression of an amino acid sequence of interest comprising combining at least two vectors with one or more restriction enzymes and optionally DNA ligase, wherein a first vector comprising a DNA sequence of interest flanked by at least two restriction enzyme sites which are sites for a first restriction enzyme which is a hapoxoterministic restriction enzyme, classified in class 435, subclass 91.52.

IV. Claim 28 -36, drawn to a method for producing a vector suitable for expression of an amino acid sequence of interest comprising combining at least two vectors with one or more restriction enzymes and optionally DNA ligase, wherein a first vector comprises a DNA sequence of interest which is flanked by at least two restriction enzyme sites wherein at least one of the flanking restriction enzyme sites is a site for a first restriction enzyme which has infrequent rest5riction sites in cDNAs or open reading frames from at least one species and generates complementary single strand DNA overhangs, wherein at least one of the flanking restriction enzyme sites is for a second restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates ends that are not complementary to the overhangs generated by the first restriction enzyme, classified in class 435, subclass 91.52

V. Claims 37, 38, drawn to a method of inducing expression of a DNA sequence of interest in a host cell comprising contacting a recombinant host cell which is deficient in rhamnose catabolism and which has a recombinant DNA molecule comprising a rhamnose-inducible promoter operably linked to an open reading frame for a heterologous RNA polymerase, with rhamnose and an expression vector comprising a promoter for the heterologous RNA polymerase operably linked to a DNA sequence of interest., classified in class 435, subclass 71.1.

VI. Claim 39, drawn to a method comprising introducing a vector comprising a nucleic acid fragment encoding a barnase which lacks a secretory domain into a recombinant host cell which expresses barstar from a promoter which is constitutively y expressed in prokaryotic cells, classified in class 435, subclass 471.

VII. Claim 40, drawn to a method comprising introducing a vector system comprising a vector, wherein the second vector comprises a counterselectable gene comprising a nucleic acid fragment encoding a barnase which lacks a secretory domain into a host cell, classified in class 435, subclass 471.

VIII. Claims 41 and 42, drawn to a vector comprising an open reading frame 3' to a DNA fragment of no more than 30 base pairs, which fragment comprising a ribosome binding site, a SgfI recognition site, and a sequence which, when present in mRNA, enhances the binding of the mRNA to the small subunit of a eukaryotic ribosome, classified in class 435, subclass 320.1.

IX. Claim 43, drawn to a vector comprising a SgfI recognition site, a sequence which comprises ATG and which sequence, when present in mRNA enhances the binding of the mRNA to the small subunit of a eukaryotic ribosome, and an open reading frame which begins at the ATG in the sequence, classified in class 435, subclass 320.1.

IX. Claims 44-55, drawn to a vector comprising a SgfI recognition site 5' to a recognition site for a first restriction enzyme which generates blunt ends, which vector once digested with SgfI and the first restriction enzyme and ligated to a DNA fragment comprising an open reading frame flanked by an end generated by a third restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends yields a recombinant vector comprising the open reading frame, classified in class 435, subclass 320.1.

X. Claim 56-58 drawn to a vector comprising a first open reading frame which includes a SgfI site and a recognition site which is not in the open reading frame for a restriction enzyme that has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, which vector, once digested with SgfI and the restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, and ligated to a DNA fragment comprising a second open reading flanked by a single stranded 3' TA DNA overhand and a blunt end, yields a recombinant vector comprising a third open reading frame comprising the first and second open n reading frames, which third open reading frame encodes a fusion peptide or protein, classified in class 435, subclass 320.1.

XI. Claims 59-65, drawn to a vector comprising a first open reading frame which includes a PmeI recognition site and is flanked at the 5' end by a recognition site for a first restriction enzyme that generates complementary single-strand DNA overhangs, classified in class 435 subclass 320.1.

XII. Claims 66-75, drawn to a method for performing genetic analysis comprising populating a database of genetic data with a plurality of genetic records, querying the database to identify a first subset of genetic records wherein each record has at least one recognition site for one predetermined restriction enzyme or for restriction enzymes included in a set of predetermined restriction enzymes, and determining a set of statistics associated with the restriction enzyme recognition sites for at least a second subset of genetic records in the first subset., classified in class 702, subclass 19.

XIII. Claim 76, drawn to a computerized system for genetic analysis, comprising a database of genetic data ad processor and asset of one or more programs executed by the processor, classified in class 710, subclass 1.

XIV. Claim 77, drawn to a vector prepared by digesting a vector comprising a SgfI recognition site 5' to a recognition site for a first restriction enzyme which generates blunt ends, with SgfI and the first restriction enzyme and ligating the digested vector to a DNA fragment comprising an open reading frame flanked by an end generated by a second restriction enzyme that generates a 3'TA overhang and an end generated by a third restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends classified in class 435, subclass 320.1.

XV. Claims 78-80, drawn to a support comprising a plurality of recombinant vectors, one or more of which comprise a different open reading frame, classified in class 435, subclass 320.1.

XVI. Claim 81, drawn to a vector prepared by the method of claim 1 comprising the first and second linear DNA molecules which are joined in an oriented manner, classified in class 435, subclass 320.1.

XVII. Claim 82, drawn to a vector prepared by the method of claim 27 comprising the first and second linear DNA molecules which are joined in an oriented manner, classified in class 435, subclass 320.1.

XVIII. Claim 83, drawn to a vector prepared by the method of claim 28, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process, such as by chemical synthesis.

Inventions of Group III and XVII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process, such as by chemical synthesis.

Inventions of Group IV and XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another materially different process, such as by chemical synthesis.

Inventions I, III, IV, V, VI, VII and XIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods have different function and effect and comprise steps which are not required for or present in the methods of the other groups: providing a first vector comprising a first selectable marker gene and a DNA sequence of interest which DNA sequence of interest is flanked by at least two restriction enzyme sites wherein at least one of the flanking restriction enzyme sites is a site for a first restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates complementary single-strand DNA overhangs, wherein at least one of the flanking restriction enzyme sites is for a second restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates ends that are not complementary to the overhangs generated by the first restriction enzyme wherein digestion of the first vector with the first restriction enzyme and the second restriction enzyme site generates a first linear DNA fragment which lacks the first selectable marker gene but comprises the DNA sequence of interest (Group I); combining at least two vectors with one or more restriction enzymes wherein a first vector comprises a first selectable marker gene and a DNA of interest, which DNA is flanked by at least two restriction enzyme sites, wherein two or more of the flanking restriction enzyme sites are sites for a first restriction enzyme which is a hapaxoterministic restriction enzyme wherein digestion of the first vector with the first restriction enzyme generates a first linear DNA fragment which lacks the first selectable marker gene but comprises the DNA sequence of interest and a first pair non-self complementary single-strand DNA overhangs (Group III); combining at least two vectors with one or more restriction enzymes wherein a first vector comprises a first selectable marker gene and a DNA sequence of interest is flanked by at least two restriction enzyme sites, wherein at least one of the flanking restriction enzyme site is a site for a first restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates complementary single strand DNA overhangs, wherein at least one of the flanking restriction enzyme sites is for a second restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates ends that are no complementary to the overhangs generated by the first restriction enzyme, wherein digestion of the first vector generates a first linear DNA fragment which lacks the first selectable marker but comprises the DNA sequence of interest (Group IV);

contacting a recombinant host cell which is deficient in rhamnose catabolism with rhamnose and an expression vector (Group V); introducing a vector comprising a nucleic acid fragment encoding barnase which lack a secretory domain into a recombinant host cells which expresses barstar from a promoter (Group VI); introducing a vector system into a host cell wherein the second vector comprises a counterselectable gene comprising a nucleic acid fragment encoding a barnase which lacks a secretory domain (Group VII); populating a database of genetic data with a plurality of genetic records, querying the database, and determining a set of statistics (Group XIII). Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The products of Group and the II, VIII, IX, X, XI, XII, XIV, XV, XVI, XVII, XVIII, and XIX are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Except for the specific relationships described above, the invention of Groups I, III, IV, V, VI, VII, XIII, and Groups II, VIII, IX, X, XI, XII, XIV, XV, XVI, XVII, XVIII, XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups II, VIII, IX, X, XI, XII, XIV, XV, XVI, XVII, XVIII, XIX are not used in or made by the methods of Groups I, III, IV, V, VI, VII, XIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
6/14/06

NANCY VOGEL
PRIMARY EXAMINER